B. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

VEGA Knee System
February 20, 2014

COMPANY: Aesculap® Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

ESTABLISHMENT REGISTRATION NUMBER: 3005673311

CONTACT: Julie Tom Wing
610-984-9147 (phone)
610-791-6882 (fax)
Julie.TomWing@aesculap.com

DEVICE

TRADE NAME:	VEGA Knee System
COMMON NAME:	Total Knee System
DEVICE CLASS:	CLASS II
PRODUCT CODE:	JWH
REGULATION NUMBER:	888.3560
CLASSIFICATION NAME:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi constrained Cemented Prosthesis

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the optional use of compatible Columbus CRA/PSA tibial plateaus and augments (K053390; K071220 and K120955) are a line extension to Aesculap's VEGA Knee System (K101281 and K121879). This line extension remains substantially equivalent to the currently marketed Aesculap Implant Systems VEGA Knee System.

DEVICE DESCRIPTION

The VEGA Knee System is a semi-constrained cemented prosthesis with a Posterior Stabilization (PS) design. The femoral component, tibial plateau and extension stem are manufactured from Cobalt Chromium Molybdenum alloy (CoCrMo) with a Zirconium nitride (ZrN) coating. The tibial "gliding surfaces" (inserts) and patella are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) and the tibial plug is made of PEEK. The system is made up of numerous components available in various sizes. The VEGA Knee System is compatible with Aesculap Columbus cruciate retaining/posterior stabilizing tibial plateau and augments (CRA/PSA). All components are sterile and for single use only.

INDICATIONS FOR USE

The VEGA Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The VEGA Knee System is designed for use with bone cement.

TECHNOLOGICAL CHARACTERISTICS (Compared to the Predicate)

The VEGA Knee System was cleared under K101281 and K121879. The fundamental scientific technology and materials for the VEGA system remain the same. The only difference is the addition of optional compatible Aesculap Columbus cruciate retaining/posterior stabilizing (CRA/PSA) tibial plateau and wedges previously cleared in 510(K) K053390, K071220 and K120955.

PERFORMANCE DATA

As a result of the risk analysis, a geometrical worse case comparison was used to determine cross compatibility of Aesculap Columbus CRA/PSA tibial plateau with Aesculap's VEGA Knee System gliding surfaces. Results of the geometrical analysis demonstrated acceptable criteria and showed that there are no new risks associated with the optional use Columbus CRA/PSA .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 25, 2014

Aesculap Implant Systems
Ms. Julie Tom Wing
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K140452
Trade/Device Name: Vega Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: JWH
Dated: February 21, 2014
Received: February 24, 2014

Dear Ms. Julie Tom Wing,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140452

Device Name
VEGA Knee System

Indications for Use *(Describe)*
The VEGA Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The VEGA Knee System is designed for use with bone cement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

PSC Publishing Services (301) 443-6740 EF

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."